

REMARKS

Applicant claims the benefits of the priority of co-pending Serial No. 09/327,717 filed June 8, 1999, now US 6,473,513, issued October 29, 2002, of which this application is a continuation. The specification has been amended to reflect the continuation in the section headed "Cross-Reference to Related Applications." The specification is further amended herein to reflect the fact that related application Serial No. 09/190,764 matured into patent No. US 6,208,741 on March 27, 2001.

Examiner's objection to the drawings is not understood. Page 20, lines 8-9 of applicant's specification states that "[t]he battery assembly 50 and microphone section 60 form a lateral section 40 when combined." Lateral section 40 is highlighted in Figs. 5, 6, 12 and 13, each of which clearly shows the medial tapering of the lateral section. Applicant requests clarification if examiner's objection has been misconstrued; otherwise, it is requested that the objection be withdrawn.

Main claims 1, 29 and 38 are amended herein. Claims 2, 4, 13, 16, 20, 23, 25-28, 36 and 37 are canceled.

In the Office Action:

(1) claims 1, 3, 4, 6-9, 11, 14, 17-19, 22-24, 29-32, 34-36 and 38 stand rejected under 35 U.S.C. 102(e) as being anticipated by Brimhall US 6,359,993 ("Brimhall");

(2) claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall in view of Devoe US 5,572,594 ("Devoe");

(3) claims 2 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall in view of Aceti US 6,473,511 ("Aceti");

(4) claims 12 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall in view of Leenen US 6,229,900 ("Leenen");

(5) claims 15, 16 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall in view of Shennib US 5,701,348 ("Shennib");

(6) claims 25, 27 and 28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shennib in view of Brimhall; and

(7) claims 10, 21, 33 and 37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brimhall.

These rejections are respectfully traversed. Each rejection is addressed below by parenthetical number, e.g., (1), as indicated above by applicant, with respect to the claims as amended herein. Claims 25-28 are among the claims canceled herein, so rejection (6) becomes moot.

Applicant's invention, as claimed in this continuation application, is directed to the single use disposable canal hearing device described in conjunction with FIG. 13, from the bottom of page 26 to the top of page 28 in applicant's specification. The device is fabricated for 'extended wear', meaning continuous placement and use of the hearing device within the ear canal without need for removal for a relatively significant period of time, at least about one week, even during periods of sleep or showering by the wearer. (Page 13, lines 4-9, emphasis added). Thus, the device does not require the customary daily removal from the ear canal characteristic of conventional CIC devices. This constitutes a significant breakthrough in hearing aid technology.

In particular, applicant's single-use disposable hearing device includes a core assembly that comprises a lateral section having a battery assembly and a microphone section. The battery assembly is integral with the lateral section so as to be non-removable from the lateral section. When the battery power is depleted, the device is simply discarded. From an economic standpoint, this makes eminent sense because the individual component and manufacturing costs are inexpensive relative to the corresponding costs for conventional CIC daily removal-type devices, and energy efficiency of the power consuming components enables battery power to be maintained over a relatively longer period of time. Lower component and manufacturing costs, combined with single use disposability and consequent elimination of restoration and repair costs, mean considerably lower purchase cost to the end user of the device, even amortized over a number of replacement purchases, relative to a typical "permanent" conventional CIC device. And this advantage is in addition to the virtual elimination of difficulties of handling and use, cost and drudgery of routine maintenance, and

physical pain suffered by the end user, compared to conventional devices.

The lateral section has an oval cross-sectional perimeter with long and short diameters. The lateral section offers an optimally comfortable fit that does not occlude the cartilaginous part of the ear canal, when suspended by a flexibly connected receiver section forming part of the core assembly in the ear canal. The receiver section is seated to occlude the ear canal in the bony part by means of a sealing retainer concentrically positioned around or over the receiver section and acoustically sealing the ear canal at that location.

An air vent in the receiver section permits pressure equalization when the hearing device is inserted into the ear canal, and when it is removed from the canal to be discarded, or when atmospheric pressures changes occur while the device is being worn in the ear canal. The air vent is of sufficiently small diameter (e.g., ≤ 0.5 mm) to impede passage of water therethrough, during showering or bathing, and even swimming. Other beneficial structure and features are described in the text of the specification concerning FIG. 13 or generic to all of the disclosed embodiments.

The background section of the specification describes some of the more problematic aspects of conventional CIC devices. Daily removal is necessary in many cases to relieve the pressures on the ear canal walls attributable to device occlusion of the cartilaginous region. And manufacturers typically recommend daily removal, particularly of CIC devices, for cleaning and maintenance, and to reduce the damaging effects of canal moisture. Wearers may suffer discomfort, irritation and pain from canal abrasion attributable to frequent insertion and removal of the device. Damage to the ear canal and the hearing device from occlusion-related moisture and cerumen production in the cartilaginous region of the canal is exacerbated during hot and humid weather, or following even relatively mild exercise. Cerumen impaction can occur when cerumen is pushed and accumulated deeper in the bony region of the canal by frequent insertion of a CIC device. And each insertion and removal of a canal device requires manual dexterity that becomes a daily challenge to the elderly hearing-impaired, especially those afflicted with arthritis, tremor, or other dexterity-limiting neurologic problems.

Main claims 1, 29 and 38, as amended, contain limitations reflecting the key structural and related functional features and characteristics of applicant's invention, and each of the dependent claims further limits its respective parent.

With reference to rejection (1), examiner asserts that Brimhall anticipates the features of applicant's invention as claimed in many of the claims, including main claims 1, 29 and 38. But, in fact, Brimhall lacks not only a teaching, but even any suggestion, of certain of the claimed features. For example, Brimhall fails to anticipate or render obvious a single use disposable hearing device adapted for continuous extended wear entirely within an ear canal as claimed in claim 1, or in the same or similar text in claims 29 and 38. Examiner contends with respect to claims 29 and 38, and presumably now to claim 1 as well, that the preamble is to be given no patentable weight regarding the intended use of the hearing device as a single use disposable device. But that contention is at odds with a considerable body of case law that holds consideration of the preamble in determining patentability (or validity) of a claim is essential where necessary or desirable for proper interpretation of the remainder of the claim.

*No consideration
of preamble*

And contrary to examiner's assertion regarding Brimhall's teaching of a hearing device adapted for extended wear, there is no 'extended wear' taught or suggested by Brimhall within the meaning of applicant's definition of that terminology (cited above). To further clarify this distinction, applicant has added the modifier 'continuous' extended wear in claims 1, 29 and 38. Brimhall's reference is to durability or reliability of his device for wear over extended periods of time, not to continuous extended wear. If it were otherwise, there would be no reason for Brimhall to utter, in the same breath (in the passage of his specification cited by the examiner) the provision of a structural component in his device "to facilitate cleaning ... when worn for extended periods of time." Many conventional CIC devices are suitable to be worn for extended periods of time, but all that are known to applicant require frequent (i.e., daily) insertion and removal principally for cleaning.

And with respect to the feature of single use disposability, applicant's claim 1, as amended, calls for a lateral section having an incorporated or integrated non-removable battery assembly to emphasize the single use disposable character of the device of applicant's

invention. In other words, regarding the period of continuous extended wear, it is limited to the period during which the battery power is sufficient to operate the device for enhancing hearing of the wearer. When the battery power is depleted or approaches depletion, the device is discarded. Hence, there is no need to make the battery removable, since it will not be replaced. This is discussed in the portion of applicant's specification accompanying FIG. 13, cited above.

Examiner contends, in the rejection of claims 29 and 38 -- which called for a single-use disposable hearing device for extended wear, with a lateral section containing a battery assembly non-removably integrated within the lateral section, even before this amendment, -- that Brimhall doesn't specifically teach that the faceplate of his device is removable so as to allow access to internal components, and hence, it appears the battery is non-removably integrated within the lateral section of his device. With all due respect, that is hardly a valid conclusion, coming from a negative hypothesis, and even if the examiner's premise were accurate. In point of fact, Brimhall says little or nothing about the battery until the embodiment of his FIGS. 7 and 8 is addressed. However, with respect to the embodiment of FIGS. 1-5, Brimhall states that "main module 14 further includes a removable faceplate 18 ... [that] allows access to the components inside the main module" (col. 4, lines 58-61; i.e., 4:58-61), one of which internal components is "a power source 36" (4:50-53). (Emphasis added). Moreover, in his discussion of the FIGS. 7-8 embodiment, Brimhall not only refers to the removable faceplate 218, but to a hinged compartment 226 accessible from the exterior of the faceplate to "allow easy replacement of the battery 236" (10:8-21). (Emphasis added). Removability and replacement of the battery logically imply removal of the device from the ear canal, from which it may be inferred that reinsertion will follow battery replacement, and that this procedure will be repeated each time the battery is replaced.

Other claim limitations in claim 1 (with similar limitations in claims 29 and 38) that are not found or suggested in Brimhall's disclosure include (i) the oval cross-sectional perimeter of the lateral section with a long diameter D_L and a short diameter D_S (Brimhall's main module 14 is circular, not oval -- whether generally or specifically; and applicant's

claims refer to the cross sectional perimeter, not the coronal view), and (ii) structure allowing the hearing device to comfortably fit in the ear canal and operate continuously therein without daily removal, for an extended period of at least one week (or a period exceeding one week (29), or a period approaching depletion of the battery power (38).

Thus, applicant's main claims distinguish patentable subject matter over Brimhall, and accordingly, so do their respective dependent claims.

Since each of rejections (2)-(5) and (7) use Brimhall as either a primary reference or a sole reference under section 103(a), the arguments in favor of patentability of applicant's claims advanced in the traversal of rejection (1) apply with equal vigor to those rejections as well. Rejection (6) is moot as noted above.

In view of the foregoing amendments and remarks, applicant respectfully urges examiner's reconsideration and withdrawal of the rejections set forth in the Office Action of 04/16/2002. Allowance of the application is solicited.

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